**Citation:**

Mennella JA. Infants' suckling responses to the flavor of alcohol in mothers' milk. *Alcohol Clin Exp Res*. 1997; 21 (4): 581-585.

**PubMed ID:** 9194908

**Study Design:**

Randomized trial

**Class:**

A - Click here for explanation of classification scheme.

**Research Design and Implementation Rating:**

POSITIVE: See Research Design and Implementation Criteria Checklist below.

**Research Purpose:**

To determine whether infants reject the flavor of alcohol in their mother's milk.

**Inclusion Criteria:**

Lactating women who had consumed at least one alcoholic beverage during lactation and whose infants had experience drinking human milk from a bottle.

**Exclusion Criteria:**

Smoking.

**Description of Study Protocol:**

**Recruitment**

Local ads in newspapers and from Women, Infant, and Children (WIC) Centers in Philadelphia.

**Design**

Randomized Trial.

**Dietary Intake/Dietary Assessment Methodology**

Interviewed about number and types of alcoholic beverages consumed during both pregnancy and lactation. The number of drinking days and the modal quantity consumed on a drinking day during lactation were also estimated to estimate frequency of exposure to the flavor of alcohol in mother's milk.

**Blinding Used**

Yes, mother's were blinded to whether they were feeding unaltered milk or milk with alcohol.

**Intervention**

- Mother's were sent a packet of nipples, bottles, and a face mask that covered the nose and mouth area to use when bottle feeding their milk to their infants during the midmorning and early afternoon feedings during the three days that preceded the testing day. Women were instructed not to eat sulfur-containing foods such as garlic, onions, or broccoli and to refrain from drinking any alcohol during the three days before testing. On the day of testing, infants were acclimated to the testing room and personnel and expressed approximately 130 ml of milk usually from both breasts, by using an electronic breast pump.
- The milk was pooled and divided into two aliquots. One aliquot remained unaltered and the other was flavored with 32 mg ethanol per dL. A two-bottle preference test (four 60-second trials) was conducted approximately 30-60 minutes before the infants next feeding. The alcohol-flavored milk was alternated with the control (unaltered milk). The mothers wore masks during the test and were not aware of why type of milk was in each bottle. The infants pattern of suckling and the amount of milk consumed during each trial was recorded. At the end of the test, mothers were asked whether they thought their infant preferred one of the bottles and if so, which one.

**Statistical Analysis**

- To determine whether infants responded differently to the alcohol-flavored milk when compared with the control, unaltered milk, paired T-test were performed for intake measures and each of the sucking parameters
- To determine whether a relationship existed between the mother's reported alcohol consumption and the infants responses to the alcohol-flavored milk, a proportional score for each of the parameters was calculated by dividing the infant's response to the alcohol-flavored milk by the response to the alcohol flavored milk plus the response to the unaltered milk.

**Data Collection Summary:**

**Timing of Measurements**

30-60 minutes before the infants next feeding session.

**Dependent Variables**

- Milliliters of intake
- Number of sucks
- Area of suck
- Number of pauses
- Sucks per burst.

**Independent Variables**

- Type of milk (alcohol-flavored or unaltered)
- Estimated number of drinks consumed by the mother per month of lactation.

**Control Variables**

None.

**Description of Actual Data Sample:**

- *Initial N:* 45
- *Attrition (final N):* 40
- *Median age:* 31.0 years
- *Ethnicity:* Not reported
- *Other relevant demographics:* There were no significant (NS) effects of the infant's sex, mother's parity or order of presentation of any of the variables tested
- *Anthropometrics:* Not reported
- *Location:* Philadelphia, Pennsylvania, US.

**Summary of Results:**

- Infants consumed significantly more ($P<0.0008$) and sucked more frequently ($P<0.019$) when drinking the alcohol-flavored milk compared with the unaltered milk
- Mother's were unaware of their infants preference during the test session as 35% of mother's thought their babies had no preference, 42% thought they preferred the alcohol-flavored milk, and 23% thought they preferred the unaltered milk
- 45% of mothers reported that they were advised to drink alcohol during breast feeding by their physician, lactation consultant or nurse
- 43% reported they were advised to drink alcohol by family members or friends
- There was a significant correlation between mother's drinking habits during lactation and the infants rhythm of sucking and frequency of sucking when feeding he alcohol-flavored milk. The greater the mean number of drinks consumed by the mother per month during lactation the less the relative number of sucks ($P=0.04$) and sucks per burst ($P=0.001$) and the greater the number of pauses ($P=0.017$) produced by infants when feeding the alcohol-flavored milk when compared with the unaltered milk. A similar relationship was obtained between the mean number of drinking days per month during lactation and the relative number of sucks per burst ($P=0.005$) and the number of pauses ($P=0.023$).

**Author Conclusion:**

The decreased milk intake by infants during breast feeding after their mother's consumption of an alcoholic beverage apparently was not due to the infants rejecting the ethanol flavor in their mother's milk. The study revealed that infant consumed and sucked more when feeding the alcohol-flavored milk, indicated that they can readily detect this flavor.

***Reviewer Comments:***

*None.*

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***Research Design and Implementation Criteria Checklist: Primary Research***

**Relevance Questions**

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| 1. | Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies) | N/A |
| 2. | Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about? | Yes |
| 3. | Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice? | Yes |
| 4. | Is the intervention or procedure feasible? (NA for some epidemiological studies) | Yes |

**Validity Questions**

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| **1.** | **Was the research question clearly stated?** | Yes |
| 1.1. | Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified? | Yes |
| 1.2. | Was (were) the outcome(s) [dependent variable(s)] clearly indicated? | Yes |
| 1.3. | Were the target population and setting specified? | Yes |
| **2.** | **Was the selection of study subjects/patients free from bias?** | Yes |
| 2.1. | Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study? | Yes |
| 2.2. | Were criteria applied equally to all study groups? | Yes |
| 2.3. | Were health, demographics, and other characteristics of subjects described? | Yes |
| 2.4. | Were the subjects/patients a representative sample of the relevant population? | Yes |
| **3.** | **Were study groups comparable?** | Yes |
| 3.1. | Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT) | Yes |
| 3.2. | Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline? | Yes |
| 3.3. | Were concurrent controls used? (Concurrent preferred over historical controls.) | Yes |
| 3.4. | If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis? | N/A |

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| 3.5. | If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.) | N/A |
| 3.6. | If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")? | N/A |
| **4.** | **Was method of handling withdrawals described?** | Yes |
| 4.1. | Were follow-up methods described and the same for all groups? | Yes |
| 4.2. | Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.) | Yes |
| 4.3. | Were all enrolled subjects/patients (in the original sample) accounted for? | Yes |
| 4.4. | Were reasons for withdrawals similar across groups? | Yes |
| 4.5. | If diagnostic test, was decision to perform reference test not dependent on results of test under study? | N/A |
| **5.** | **Was blinding used to prevent introduction of bias?** | Yes |
| 5.1. | In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate? | Yes |
| 5.2. | Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.) | Yes |
| 5.3. | In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded? | N/A |
| 5.4. | In case control study, was case definition explicit and case ascertainment not influenced by exposure status? | N/A |
| 5.5. | In diagnostic study, were test results blinded to patient history and other test results? | N/A |
| **6.** | **Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?** | Yes |
| 6.1. | In RCT or other intervention trial, were protocols described for all regimens studied? | Yes |
| 6.2. | In observational study, were interventions, study settings, and clinicians/provider described? | N/A |
| 6.3. | Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect? | Yes |
| 6.4. | Was the amount of exposure and, if relevant, subject/patient compliance measured? | Yes |

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| 6.5. | Were co-interventions (e.g., ancillary treatments, other therapies) described? | Yes |
| 6.6. | Were extra or unplanned treatments described? | N/A |
| 6.7. | Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups? | Yes |
| 6.8. | In diagnostic study, were details of test administration and replication sufficient? | N/A |
| **7.** | **Were outcomes clearly defined and the measurements valid and reliable?** | Yes |
| 7.1. | Were primary and secondary endpoints described and relevant to the question? | Yes |
| 7.2. | Were nutrition measures appropriate to question and outcomes of concern? | N/A |
| 7.3. | Was the period of follow-up long enough for important outcome(s) to occur? | Yes |
| 7.4. | Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures? | Yes |
| 7.5. | Was the measurement of effect at an appropriate level of precision? | Yes |
| 7.6. | Were other factors accounted for (measured) that could affect outcomes? | Yes |
| 7.7. | Were the measurements conducted consistently across groups? | Yes |
| **8.** | **Was the statistical analysis appropriate for the study design and type of outcome indicators?** | Yes |
| 8.1. | Were statistical analyses adequately described and the results reported appropriately? | Yes |
| 8.2. | Were correct statistical tests used and assumptions of test not violated? | Yes |
| 8.3. | Were statistics reported with levels of significance and/or confidence intervals? | Yes |
| 8.4. | Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)? | N/A |
| 8.5. | Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)? | Yes |
| 8.6. | Was clinical significance as well as statistical significance reported? | Yes |
| 8.7. | If negative findings, was a power calculation reported to address type 2 error? | No |
| **9.** | **Are conclusions supported by results with biases and limitations taken into consideration?** | Yes |
| 9.1. | Is there a discussion of findings? | Yes |

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| 9.2. | Are biases and study limitations identified and discussed? | Yes |
| **10.** | **Is bias due to study's funding or sponsorship unlikely?** | Yes |
| 10.1. | Were sources of funding and investigators' affiliations described? | Yes |
| 10.2. | Was the study free from apparent conflict of interest? | Yes |